

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of)	ADMINISTRATIVE COMPLAINT
)	FOR CIVIL MONEY PENALTIES
GERALD DORROS, M.D.,)	
)	
an individual.)	FDA Docket No. <u>2005H-0099</u>
)	
)	

SETTLEMENT AGREEMENT

THIS SETTLEMENT AGREEMENT is made this 1st day of March, 2005, by and between Complainant Food and Drug Administration ("FDA") Center for Devices and Radiological Health ("CDRH") and Respondent Gerald Dorros, M.D. ("Dorros").

WHEREAS, CDRH filed an administrative complaint for civil money penalties against Dorros, a copy of which is attached hereto and incorporated herein, alleging that Dorros violated 21 U.S.C. § 331(a) on at least two occasions by introducing into interstate commerce devices that were adulterated within the meaning of 21 U.S.C. 351(f)(1)(B) in that they were Class III devices that were required to, but did not, have in effect an approved PMA, nor were they subject to an exemption from the PMA requirement;

WHEREAS, FDA and Dorros have engaged in discussions directed to the resolution of this civil money penalties action;

WHEREAS, these discussions have resulted in compromise and settlement, as set forth herein, and FDA and Dorros, without admitting or denying the allegations in the Complaint, hereby agree to the following:

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SET 1

1. The Secretary of Health and Human Services has subject matter jurisdiction over this action pursuant to 21 U.S.C. § 333(f) and has delegated his functions to the Commissioner of Food and Drugs under 21 U.S.C. § 5.10(a). FDA has personal jurisdiction over Respondent Dorros pursuant to 21 U.S.C. § 333(f). Pursuant to 5 U.S.C §§ 554 and 556, 21 U.S.C. § 333(f)(3)(A), and the implementing regulations at 21 C.F.R. Part 17, an administrative law judge appointed according to 5 U.S.C. § 3105 has the authority to conduct a civil money penalty hearing and assess a civil penalty.

2. This Settlement Agreement is being executed contemporaneously with a misdemeanor criminal plea agreement and civil settlement between Dorros and the United States. In remedy of the alleged violations, Dorros agrees to pay a civil money penalty of \$30,000. This amount shall be due and payable no later than 10 days from the date of the sentencing pursuant to the contemporaneous criminal misdemeanor plea.

3. All parties waive any right to a hearing under 21 U.S.C. § 333(f), and any other right that they may have to contest or appeal the imposition or amount of civil money penalties herein assessed.

4. In the event that Respondent fails to make timely payment of the amount specified in this Settlement Agreement, interest shall automatically accrue on all unpaid amounts at the rate of 15% *per annum*, compounded daily, commencing on the date that payment is due. Complainant may proceed against Respondent for collection of any and all amounts owed by Respondent, including any unpaid balance and interest.

5. If Complainant is required to take administrative or judicial action to enforce this Settlement Agreement, Respondent shall be liable for Complainant's costs of such action, including reasonable attorney fees.

6. Complainant and Respondent shall bear their own costs, including attorney fees, relating to the action underlying this Settlement Agreement.

7. The administrative law judge shall retain jurisdiction of this action until the full amount of the penalty due herein and any interest, if accrued, are paid. Upon final payment of such amounts, Complainant shall file a Joint Stipulation for Dismissal with Prejudice with the administrative law judge.

8. This Settlement Agreement fully resolves and settles all claims in the Administrative Complaint for Civil Money Penalties against Respondent Gerald Dorros, M.D., and any and all claims or actions which could be initiated by FDA or brought under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., or regulations promulgated thereunder related to the facts circumstances, events, medical procedures, or violations alleged in the Complaint to the extent that such claims or actions or potential claims or actions are based on facts, circumstances, events, or violations that predate the filing of the Complaint. Specifically reserved and excluded from the scope and terms of this Settlement Agreement as to any entity or person (including Dorros) are any criminal liability or any civil or administrative monetary claim the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

IT IS SO ORDERED:

Dated this 10th day of March, 2005.

/s/ Daniel J. Davidson
DANIEL J. DAVIDSON
Administrative Law Judge